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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/077,214	05/26/98	SCHMIDT	0652.1710000

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STERNE KESSLER GOLDSTEIN & FOX  
1100 NEW YORK AVENUE NW  
SUITE 600  
WASHINGTON DC 20005-3934

EXAMINER

SCHWADRON, R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 08/16/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

# Office Action Summary

Application No.  
09/077,214

Applicant(s)  
Schmidt et al.

Examiner  
Ron Schwadron, Ph.D.

Group Art Unit  
1644



- ☐ Responsive to communication(s) filed on \_\_\_\_\_
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

- ☒ Claim(s) 36-68 is/are pending in the application.
- Of the above, claim(s) 37, 41, 45-47, and 51-68 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 36, 38-40, 42-44, and 48-50 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☒ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- ☒ Notice of References Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Applicant's election without traverse of Group I, claims 36-50,53,54 in Paper No. 11 is acknowledged.
2. Claims 51,52,55-68 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions. Election was made **without** traverse in Paper No. 11.
3. Applicant's election without traverse of the species recited in Paper No. 14 is acknowledged.
4. Claims 37,41,45-47,53,54 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions. Election was made **without** traverse in Paper No. 14.
5. Claims 36,38-40,42-44,48-50 are under consideration. Claims 1-35 have been cancelled.
6. Regarding the IDS filed 4/6/1999, the Nabel et al. reference is considered on the enclosed PTO-892. Regarding WO 94/21808, said German language publication was considered only with respect to the English language abstract.
7. Claims 48-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 48 is indefinite in the recitation of "charged" because it is unclear what this term means or encompasses.
8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention

thereof by the applicant for patent.

9. Claims 36,38-40,42,43 are rejected under 35 U.S.C. 102(e) as being anticipated by Dow et al. (US Patent 5,705,151) as evidenced by Haeffner et al. and prior art disclosed in the specification (see page 3).

Dow et al. teach allogeneic tumor cells that have been transfected with nucleic acids encoding a superantigen (see column 13 and column 6) wherein said cells are used as a tumor vaccine. Haeffner et al. establish that the art recognized that superantigens can be presented in the context of MHC class I when presented by cells which do not express MHC class II. Dow et al. teaches that the claimed invention can be practiced with a variety of tumor cells which the art recognizes do not express MHC class II (see column 14). Thus, it is an inherent property of the tumor vaccine disclosed by Dow et al. that the superantigen produced by the transfected tumor cell is presented in the context of MHC class I. Dow et al teach that the superantigen can be of viral origin (see column 2). The art recognizes that tumors express numerous different tumor associated antigens (see prior art disclosed in specification, page 3)

10. Claims 36,38-40,42-44,48-50 are rejected under 35 U.S.C. 102(a) as being anticipated by Schmidt et al.

Schmidt et al. teach the claimed invention (see abstract and pages 9761-9763). This rejection can be overcome by supplying a certified English language translation of the foreign priority documents to which the instant application claims priority (assuming said documents disclose the claimed invention).

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 36,38-40,42-44,48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable

over Fearon et al. in view of Townsend et al., Dow et al. (US Patent 5,705,151) , Haeffner et al. and prior art disclosed in the specification (see page 3).

Fearon et al. teach a tumor vaccine wherein tumor cells are transfected with the gene encoding HA (see entire paper). Fearon et al. do not disclose an allogeneic human tumor vaccine. Townsend et al. teach that influenza HA or NP peptides are recognized by CTL in the context of MHC class I. Dow et al. teach allogeneic human tumor cells that have been transfected with nucleic acids encoding an antigen recognized by T cells (see column 13 and column 6) wherein said cells are used as a tumor vaccine. Haeffner et al. establish that the art recognized that superantigens can be presented in the context of MHC class I when presented by cells which do not express MHC class II. Dow et al. teaches that the claimed invention can be practiced with a variety of tumor cells which the art recognizes do not express MHC class II (see column 14). Thus, in the tumor vaccine disclosed by Dow et al. the antigen produced by the transfected tumor cell is presented in the context of MHC class I. Dow et al teach that the antigen can be of viral origin (see column 2). The art recognizes that tumors express numerous different tumor associated antigens (see prior art disclosed in specification, page 3). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Fearon et al. teach a tumor vaccine wherein tumor cells are transfected with the gene encoding HA while Dow et al. teach allogeneic human tumor cells that have been transfected with nucleic acids encoding an antigen recognized by T cells wherein said cells are used as a tumor vaccine. In view of the fact that the cells disclosed by Fearon et al. were transfected with intact HA, said cells would have been expected to present multiple different peptides representing different epitopes derived from said molecule. It would also be expected that said HA would encode a variety of different epitopes that would bind different HLA molecules found on MHC antigen heterozygous human tumor cells. Regarding the term "charged", while it is unclear what said term means, for the purposes of this rejection it will be interpreted as encompassing a peptide added to a cell via nucleic acid transfection. One of ordinary skill in the art would have been motivated to do the aforementioned because of the demonstration by Fearon et al. of the use of HA transfected tumor cells as a tumor vaccine.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official

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Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

14. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ms Christina Chan can be reached on (703) 308-3974. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON  
PRIMARY EXAMINER  
GROUP 1600 1600



Ron Schwadron, Ph.D.

Primary Examiner

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